who used combination therapy (topical corticosteroid and TCI) (68%). Type of health plan, Medicaid eligibility status, number of therapeutic class, comorbidity, hospitalization or not and AD related costs during 12 months before AD medication started were significantly associated with AD medication adherence. Adherence to AD medication was significantly negatively associated with total annual healthcare costs ($p<0.001$) and with AD related costs ($p<0.001$), adjusted for patient demographic, comorbidity, and healthcare utilization characteristics before AD medication started. **CONCLUSIONS:** Poor adherence to topical medication was observed in pediatric AD, and adherence rates differed by the type and combination of AD medication therapy. The detrimental effect of poor adherence on healthcare economic outcome was significant, which implies a need to improve adherence in order to reduce the financial impact of non-adherence. Factors which could contribute non-adherence and financial burden need to be refined and targeted by intervention to improve humanistic and economic outcomes of treatment.

PSS26

PATIENT'S EVALUATION OF THE QUICKNESS OF ACTION OF GINGIVAL INFLAMMATION TREATMENTS

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OBJECTIVES: Gingivitis is defined as lesions on the gingival margin, expressed through gum redness, bleeding, localized edema, and gingival sensitivity. It is most often caused by substances produced by bacterial plaque, or dental biofilm, which develops along the gingival crevice.To evaluate, using patient's interview results, the quickness of action of several treatments for gingival inflammation. **METHODS:** Observational, prospective, longitudinal, multicentric study carried out in France, using data collected by participating dentists and dental surgeons. **RESULTS:** A total of 316 patients with gingivitis returned their questionnaire. women: 65.25%, current smokers:22.93% and 28.51% were ex-smokers. Light and heavy bleeding during brushing was reported by 45.74% and 33.33% of patients respectively. 45.70% reported visible redness, 56.34% reported swollen gums, 13.19% had lesions, but above all 50.52% reported pain. Finally, 62.26% had previous history of gingivitis symptoms. As for dental surgeons: 96.36% had performed scaling, 15.15% gingival curettage, and 13.64% radicular resurfacing. A total of 78.4% judged gingival inflammation to be moderate to severe, 63.10% said it had spread (>30%). In terms of treatment: 98.62% gave patients oral hygiene advice, 87.98% advised on brushing methods, 69.91% recommended specific toothpaste, and 78.85% a mouthwash. A total of 30.61% had generalized inflammation after 1 month, reducing to just 11.24% at 2 months and 15.63% at 3 months. A total of 88.08% reported improvement in inflammation after the first month, 91.59% at 2 months and 93.59% at 3 months. A total of 83.93% felt less pain after 1 month of treatment, 87.90% after 2 months and 92.08% after 3 months.($p=0.0418$). 89.13% felt their treatment was effective after 1month, 97.79% after 2 months and 96.15% after 3 months.($p=0.0036$). **CONCLUSIONS:** In terms of satisfaction, 86.52% were satisfied after 1 month, 94.85% after 2 months and 95.92% after 3 months. ($p=0.0076$). 87.57% felt their treatment was easy to follow after 1 month, 86.76% after 2 months and 92.08% after 3 months. Above all, after the first month of treatment, 88.83% said they would continue using the treatment in prevention even after complete disappearance of gingivitis.

Sensory Systems Disorders – Research on Methods

PSS27

EFFECT OF TREATMENT SWITCH ON THE COST-EFFECTIVENESS OF BIOLOGICS IN PSORIASIS IN PERU AND COLOMBIA

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OBJECTIVES: To evaluate the effect of treatment switch on the cost-effectiveness of biologics used in patients with moderate or severe psoriasis in Colombia and Perú. **METHODS:** In a previous study (Alandete, JC accepted in the ISPOR 13th Anual European Congress) cost effectiveness of etanercept, adalimumab, ustekinumab and infliximab was estimated based on label information for first-(induction) year and second(maintenance) year assuming a 100% treatment continuation ($1USD=COL$1.832=SOL$2.75). For etanercept two induction schemes were considered: 50mg weekly 52 weeks-D1- and 100mg 12 weeks followed by 50 mg 40 weeks-D2-. Effectiveness was evaluated as 75% reduction in Psoriasis Area and Severity Index-PASI 75- infliximab=80%; ustekinumab=69%; adalimumab=59%; etanerceptD2-=52%; etanerceptD1=39%. Infliximab and ustekinumab effectiveness were not significantly different. Both were significantly superior to etanercept (Hawkins et al. meta-analysis presented in the 14th International ISPOR). In this abstract we developed a new model estimating switching probabilities due to treatment failure at week 12 and adverse events. Biologics costs were adjusted considering time on the pre and post-switching periods. Treatment effectiveness was adjusted when biologics were used after switching due to treatment failure. **RESULTS:** Introduction of switching effect ratified ustekinumab dominance in Colombia ($US44,675 in 2 years) generating cost savings of -$US4.049 versus etanerceptD1; -$US4.049 versus adalimumab; -$US7.844 versus etanerceptD2 and -$US27.517 versus infliximab; with higher or same effectiveness than the other biologics in that country. In Peru, ustekinumab changed from being the most cost-effective option and became the dominant option ($US41.827 in 2 years) generating cost savings of -$US283 versus etanerceptD1; -$US489 versus adalimumab; -$US3581 versus etanerceptD2 and -$US13.499 versus infliximab. **CONCLUSIONS:** In the studied countries inclusion of the switching effect due to treatment failure and adverse events ratifies cost-savings observed in Colombia and makes ustekinumab the cost-saving option in Peru. These results corroborate those observed in the USA and Europe.

PSS28

EFFECT OF DIFFERENT RECALL PERIODS ON DRY EYE SYMPTOM RATINGS

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OBJECTIVES: Clinical studies of dry eye disease (DED), a highly symptomatic disease, often ask patients to evaluate their DED symptoms using patient-reported outcomes instruments. Most of these instruments use a one-week recall period. The effect of this recall period on the accuracy of DED symptom assessments has not been documented. The purpose of our research was to compare self-reported DED symptoms between one-week and daily recall periods. **METHODS:** We enrolled 156 DED patients to a web-based observational study to assess their DED symptoms once a day for 9 days. For each of the 14 symptoms, we asked the patients to rate the frequency and intensity on a 0-6 rating scale, with a higher score indicating worse symptom. The assessments on Days 1 and 9 had a one-week recall period, while the assessments on Days 2-8 had a one-day recall period. We then calculated the mean weekly scores for Day 1 and Day 9 and the mean daily scores for Days 2-8, and tested the differences between the mean weekly and daily scores using matched-pair t tests without multiplicity adjustment. **RESULTS:** The Day 1 mean weekly scores were significantly higher than the mean daily scores for all 14 symptoms in both frequency and intensity. The Day 1 mean weekly scores were also significantly higher than the Day 9 mean weekly scores in 10 frequency and 11 intensity scores. The Day 9 mean weekly scores were slightly higher than the daily scores; however, most of the differences were not statistically significant. **CONCLUSIONS:** Patients' self-ratings of their DED symptoms using a one-week recall period are consistently inflated when compared to their ratings using a one-day recall period. Such inflation should be considered when designing clinical studies for DED.

PSS29

DEVELOPMENT OF THE MODIFIED OCULAR COMFORT INDEX (MOCI)

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OBJECTIVES: Dry eye disease (DED) is characterized by symptoms of ocular discomfort, visual disturbance and reduced tolerance to environmental stressors. DED has a significant negative impact on the quality of life (QOL) of persons affected, and imposes a massive burden on medical resources owing to its high prevalence and chronic nature. It is not known if available patient-reported outcome (PRO) instruments fully capture the scope of DED symptoms and their impact on QOL. The purpose of our ongoing research is to develop a PRO instrument that meets the needs of clinical studies investigating potential treatments for DED. **METHODS:** Patients with DED in five countries (United States, United Kingdom, Spain, Japan and Korea) were interviewed to identify their symptoms and the impact of the disease on QOL (n=120). Based on these results, items were drafted that were tested in two web-based studies with mild-moderate DED subjects (n=106 and 156) and face-to-face interviews with severe DED subjects (n=22). **RESULTS:** Items enquiring about 8 additional symptom experiences (16 items grouped in doublets asking about frequency/intensity) were added to the original Ocular Comfort Index (OCI) using the same question format and response structure (fluctuating vision, light sensitivity, redness, foreign body sensation, excessive tearing, excessive blinking, ocular irritation and stickiness). Additionally, 2 items that enquired about the most bothersome symptom and the extent of bother, and 12 items that appraised how symptoms interfered with the ability to perform daily activities were included. **CONCLUSIONS:** Patient interviews suggest that available PRO instruments do not fully capture the scope of DED symptoms and their impact on QOL. The modified OCI (mOCI) will be used in clinical studies to facilitate its refinement and validation.

PSS30

BURDEN OF INFANTILE HEMANGIOMA: DEVELOPMENT OF A QUESTIONNAIRE

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OBJECTIVES: Infantile hemangioma (IH) develops during the first weeks of life; it normally forms within 3to6 months, then regresses very slowly over a duration of 3 to 7 years. In complicated forms, it is possible to encounter haemorrhaging, necroses and ulcerations, infections and, more exceptionally, respiratory distress, cardiovascular shunt. To explore the handicap, in its largest sense, generated by IH using a questionnaire to express the burden on the daily life of the parents. **METHODS:** The questionnaire was developed following a strict methodological process, involving a multidisciplinary team incorporating various players (doctors, nurses, social workers) who are involved in the treatment of patients or who are specialised in the construction of questionnaires. A review of the literature and discussions with the families were conducted in order to identify the concepts related to the pathology. **RESULTS:** Exploratory assessments showed that the concept of burden could be structured around two main modules: assess the impact directly for the first-module. The consequences of HI on daily life, family and personal relationships, work, financial situation and psychological impact for the second-module. A third module focuses on the behaviour of the child; this module will evolve over time and depending on the analyses. Fifty-six preliminary items were identified following a first discussion. A first analysis managed to reduce these items to 36 whilst conserving the 3 modules but making it easier to use the analysis. **CONCLUSIONS:** The Hemangioma-Burden-Questionnaire will allow clinicians to better understand the impact and consequences of the pathology on the family. It will also allow the development of the burden to be monitored according to the rate of development of the illness and its treatment.It will also allow the

families of the children to better defend their interest before the health authorities in terms of expenditure (medical or other) for which the part remaining their responsibility is increasing significantly.

Systemic Disorders/Conditions – Clinical Outcomes Studies

PSY1

SEVERE RENAL, HEPATIC AND GASTROINTESTINAL EVENTS ASSOCIATED WITH DEFERASIROX IN PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA

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OBJECTIVES: Iron chelators (deferasirox or desferrioxamine) are essential to patients who need life-long blood transfusion (e.g. β-Thalassemia). However, in 2010, the US Food and Drug Administration (FDA) had issued a warning on potential adverse events associated with iron chelators, especially deferasirox. The objective of this retrospective cohort study was to compare the risk of renal impairment, hepatic impairment, and gastrointestinal bleeding in patients with transfusion-dependent anemia using deferasirox or desferrioxamine. **METHODS:** Patients with transfusion-dependent anemia (sickle cell disease, β-thalassaemia, myelodysplastic syndrome and aplastic anemia) and were prescribed iron chelators (deferasirox or desferrioxamine) were identified from the 2005−2009 Taiwan's National Health Insurance database. Cox proportional hazards models were used to assess the association between iron chelators and occurrences of adverse events (renal impairment, hepatic impairment, and gastrointestinal bleeding). All models adjusted for age, sex, drug exposure (days), type of transfusion-dependent anemia and medical history. **RESULTS:** Patients were categorized into deferasirox (n=180), desferrioxamine (n=586),and mixed users (n=202), based on the drug they received during the follow-up. The crude rates of adverse events were 4.14, 3.16 and 0.65 per 10,000 person-year in deferasirox, desferrioxamine and mix users, respectively. After adjusting covariates, there was no association between deferasirox and adverse events (hazard ratio [HR]0.84; 95% CI, 0.59–2.00) compared to desferrioxamine users. **CONCLUSIONS:** In this population-based analysis, transfusion-dependant anemia patients using deferasirox and desferrioxamine were at similar risk of adverse events.

PSY2

THE ASSOCIATION BETWEEN THERAPY WITH ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND HEMOGLOBIN LEVEL

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OBJECTIVES: To assess the hematological effects Angiotensin-converting enzyme (ACE-I) inhibitors and Angiotensin II receptor blockers (ARB) in patients without concomitant renal impairment. **METHODS:** In the present retrospective cohort study we used the Maccabi Healthcare Services' database to identify new users of ACE-I (N=14754) ARB (N=751), or calcium channel blockers (CCB, N=3087) with available hemoglobin (Hb) tests between 2004 and 2009. Excluded were patients purchasing drugs from more than one medication class, diagnosed with renal impairment or cancer. Median Hb levels one year before and after first medication purchase (index date) were calculated and compared according to the proportion of days covered with medication class. **RESULTS:** Persistent use of ACE-I and ARB was associated with a significant decrement in hemoglobin level. Patients at the highest PDC level were at a significantly higher risk of developing anemia among ACEI (OR = 1.59, p<0.001), and ARB (OR = 2.21, p=0.05). The relationship between CCB therapy and Hb decrement was substantially weaker. **CONCLUSIONS:** Hb levels are reduced during the first year of ACE-I or ARB therapy. This association is dose-dependent and is not likely to be caused by artifacts related to patient adherence.

PSY3

OPIOIDS IN NON-MALIGNANT PAIN: ARE THEY EQUIVALENT IN SAFETY PROFILE? A NETWORK META-ANALYSIS

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OBJECTIVES: Severe non-malignant pain affects a large number of patients. Opioids are an important option for analgesia. However, there is relatively little information about the comparative safety of opioids. We sought to compare the safety and tolerability of commonly used opioids in non-malignant pain through network meta-analyses of randomized controlled trials (RCTs). **METHODS:** Medline and Embase were searched from 2000 to 2011 for RCTs comparing commonly used opioids (tramadol, oxycodone, hydrocodone, propoxyphene, codeine) in non-malignant pain. Studies were assessed for inclusion/exclusion based on a prespecified protocol. Two reviewers undertook data extraction independently. Any disagreement was resolved by a third reviewer. A network meta-analysis was used to combine direct and indirect evidence for safety outcomes reported in the trials. Based on the incidence of adverse events (AEs) for each intervention, a probability-based ranking (probability (P) of being worst) was generated using WinBUGS. **RESULTS:** Of the 1156 studies, 5 RCTs enrolling 1399 patients were eligible for inclusion. The most commonly reported AEs were nausea, vomiting, somnolence, dizziness, headache, constipation and dry mouth. Withdrawals due to AEs were most commonly observed with codeine (P=42%) followed by hydrocodone (P=28%), tramadol (P=19%), and oxycodone (P=10%). The probability of occurrence of nausea and somnolence was the highest with codeine. Dizziness was most frequently associated with oxycodone (P= 53%). However, the incidence of dizziness and headache was the lowest with codeine. Tramadol was observed to be associated with the highest (P=40%) incidence of vomiting, while hydrocodone had the lowest incidence (P=15%). **CONCLUSIONS:** Codeine was observed to have the highest incidence of withdrawals due to AEs. It was observed that the probability of occurrence of any particular AE varied across included opioid analgesics. Codeine was observed to have been more frequently associated with nausea/somnolence while tramadol and oxycodone had the highest incidence of vomiting and dizziness respectively.

PSY4

TRENDS IN HYPONATREMIA MANAGEMENT AND ASSOCIATED OUTCOMES IN HOSPITAL SETTINGS: INTERIM RESULTS FROM AN OBSERVATIONAL, PROSPECTIVE, MULTI-CENTER, GLOBAL REGISTRY IN HOSPITALIZED PATIENTS

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OBJECTIVES: Although hyponatremia (HN) is the most common electrolyte abnormality in hospitalized patients, little is known regarding the influence of HN and its management on patient outcomes and healthcare resource usage. The HN Registry is a novel prospective effort to document the clinical and healthcare outcomes of HN and its management. Results for the first 25 HN patients enrolled are described here. **METHODS:** After informed consent or waiver, data were extracted from medical charts of enrolled patients. HN was defined as a serum sodium ≤ 130 mmol/L. The pilot data were summarized appropriately by sample size and for categorical data by percentage. Subjects who had HN on admission were categorized as pre-existing HN patients and those who were admitted for another reason and developed HN while in the hospital were categorized as hospital-acquired HN patients. **RESULTS:** Overall, only 20% of the enrolled patients received any pharmacologic management for HN and approximately 44% were discharged with persistent HN (21% of treated vs. 79% of untreated). Among the patients discharged with HN, 55% had a previous episode of HN. In addition, among the patients with previous HN, 46% were discharged with persistent HN. The length of stay for patients with pre-existing HN was 1.3 days longer compared to patients with hospital-acquired HN. These findings will be further evaluated and reported as more data in this large registry study are accumulated. **CONCLUSIONS:** Among hospitalized patients, HN is frequently untreated, and nearly half of patients are discharged without normalization of serum sodium. HN commonly persists through several hospital admissions.

PSY5

AN INVESTIGATION INTO THE RELATIONSHIP BETWEEN OBESITY AND SKIN AND SOFT TISSUE INFECTIONS REQUIRING HOSPITALIZATION

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OBJECTIVES: The United States is experiencing an obesity epidemic with 67% of adults being either overweight or obese. While it is known that excessive weight increases the opportunity for skin infections, this relationship has not been well studied. This study contributes to the knowledge about the relationship between these two conditions. **METHODS:** Using the H-CUP national database for inpatient hospitalizations, this study analyzed the data from hospitals in the Southern states for the number of skin and soft tissue infections in 2003, 2005 and 2007 in adults. The proportion of patients who were also coded as obese in this population was quantified. Two t-tests were performed comparing the average length of stay for patients who were obese and not obese and the average total hospital charges for patients who were obese and not obese. Two linear regressions analyzed the impact of obesity on the cost of health care by using length of stay and total hospital charges as dependent variables. **RESULTS:** The proportion of patients hospitalized for skin and soft tissue infections who were also obese increased from 48.09% in 2003 to 51.7% in 2007. The average length of stay was 7.97 days for non-obese patients verses 4.6 days for patients coded as obese which was statistically significant. The average total hospital charges were $26,653 for non-obese patients compared to $20,876 for obese patients. This was also statistically significant. Surprisingly, the co-morbidity of obesity has a negative predictive value for both hospital length of stay and total hospital charges. **CONCLUSIONS:** It is possible that patients who are obese are being discharged sooner because of differences in severity of infections. More research is needed to determine whether obesity is a causal factor in skin and soft tissue infections and how this is affecting the cost and delivery of health care.

PSY6

TRANSFUSIONAL IRON OVERLOAD (TIO) MONITORING AND TREATMENT: FINDINGS FROM AN ELECTRONIC MEDICAL RECORDS REVIEW STUDY AT THE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE

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OBJECTIVES: We examined proportions of patients: a) monitored for TIO after receiving ≥10, ≥20, and ≥30 units of red blood cells (RBC) and b) receiving iron chelation therapy (ICT). We also examined overall survival (OS) among: a) monitored vs. unmonitored; b) ICT-treated vs. ICT-untreated groups. **METHODS:** Medical records of patients >18 years receiving ≥10 RBC units ≥6 months before data abstraction were identified at the Moffitt Cancer Center and Research Institute (December 2009-June 2010). Observation period spanned from 10th RBC unit to end of follow-up (i.e., death, clinic departure, or end of observation period). TIO moni-